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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,695	02/12/2001	Terrence L. Graham	22727/04056	6144
24024	7590	07/27/2006		EXAMINER
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			PRYOR, ALTON NATHANIEL	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/781,695	GRAHAM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 05 May 2006.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 12-20,23 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 23 is/are allowed.

6) Claim(s) 12 and 15-20 is/are rejected.

7) Claim(s) 13 and 14 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_.

I. Rejection of claim 23 under 35 USC 102(b) as being anticipated by Ellis will not be maintained in light of amendment filed 5/5/06. Applicant has delete "orthovanadate" from the claim 23.

II. Rejection of claim 23 under 35 USC 103(a) as being obvious over Passilly will not be maintained in light of amendment filed 5/5/06. Applicant has delete "orthovanadate" from the claim 23.

III. Rejection of claims 12,15-20 under 35 USC 112, 1<sup>st</sup> paragraph will be maintained in light of amendment filed 5/5/06 for reason on record and reason as follows.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12,15-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (*In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
  
- 8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is to a method of inducing production of isoflavones in a plant comprising applying to the plant a composition comprising a compound of formula V and one or more b compounds selected from 1) compounds that enhance the release of isoflavones from sugar conjugates 2) compound that enhance the incorporation of aglycones into glyceollin and 3) Compounds that enhance the release of isoflavones from sugar conjugates and incorporation of aglycones into glyceollin.

2) State of the prior art and the predictability or lack thereof in the art.

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which b compounds when combined with compound of formula V exhibited the desired isoflavone production. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant claimed invention is highly unpredictable as discussed below:

It is noted that the art of producing isoflavone in plants is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Further, their mode of action is often unknown or very unpredictable and administration of the b compounds can be accompanied by undesirable side effects.

Thus, in the absence of a showing of correlation between all classes of b compounds and isoflavone production in plants as claimed, one of ordinary skill in the art is unable to fully predict possible results from the application of the b compounds due to the unpredictability of the role of the huge number of b compounds set forth in the claims.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would first need to determine the types of b compound and how their combination with compounds of formula V will induce production of isoflavone.

5) Amount of direction and guidance provided by the inventor.

The amount of direction or guidance present is found on pages 17-24 wherein only experimental data for orthovanadate as the b compound is provided.

6) Existence of working examples.

Working examples are found on pages 17-24 only support the use of orthovanadate as the b compound. Applicant's limited working example does not enable one of ordinary skill in the art to induce isoflavone production by plants with all claimed b compounds as encompassed by the instant invention.

7) Breadth of claims.

Claims are extremely broad due to the vast number of possible b compounds encompassed by the instant invention.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Due to the unpredictability in the art, it is noted that each embodiment of the invention is required to be individually assessed for plant physiological activity by *in vitro* and *in vivo* screening to determine which b compounds exhibit the desired activity when combined with the compounds of formula V.

Hence, the specification fails to provide sufficient support of the use of the b compounds of the claims for inducing the production of isoflavones by plants. As a result necessitating one of ordinary skill in the art to perform an exhaustive search to determine which b compounds of the instant claims can promote or induce isoflavone production by the plants in order to practice the claimed invention.

*Genentec Inc. V. Novo Nordisk A/S* (CAFC) 42 USPQ 2D 1001, states that:

“a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test for which b compounds can induce isoflavone production by the plants, with no assurance of success.

Applicant argues that ample guidance in specification is provided for selecting agents that enhance the activity of nuclear receptor ligands. For example, Applicant set forth enhancers such as ion effectors and elicitors of the phytoalexin glyceollin for

inducing the production of isoflavones by plants. Applicant suggests that claimed method coupled with prior art knowledge may be used to determine which b compounds - other than copper salt, orthovanadate, rose Bengal or a tetrazolium redox dye - would induce production of isoflavones by plants. Examiner argues that claim 12 claims broad classes of b compounds. In order for an artisan to determine which compounds would be effective in instant method, an artisan would have to test numerous classes of the claimed compounds for their activity for inducing the production of isoflavone by plants. Applicant only provides data for orthovanadate as the b compound. For this reason, applicant's method does not provide adequate guidance for selecting which other b compounds would be effective in said activity. The prior art discloses millions of b compounds. However it would be an undue burden for an artisan to determine which compounds in the millions would be effective in inducing isoflavone production by plants.

***Claim Objection / Allowable Subject Matter***

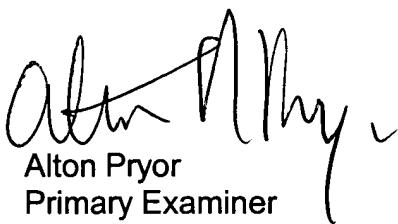
Claims 13,14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest instant invention comprising orthovanadate, rose Bengal, a tetrazolium redox dye, or copper salt. Claim 23 is allowable. The prior art does not teach or suggest the instant invention comprising ion effectors, rose Bengal or tetrazolium redox dyes.

***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Alton N. Pryor  
Primary Examiner  
AU 1616